

STATE OF MICHIGAN
DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
OFFICE OF FINANCIAL AND INSURANCE REGULATION
Before the Commissioner of Financial and Insurance Regulation

In the matter of

XXXXXX

Petitioner

v

File No. 122937-001

Golden Rule Insurance Company

Respondent

Issued and entered
this 20th day of January 2012
by R. Kevin Clinton
Commissioner

ORDER

I. PROCEDURAL BACKGROUND

On August 18, 2011, XXXXX, authorized representative of XXXXX (Petitioner), filed a request for external review with the Commissioner of Financial and Insurance Regulation under the Patient's Right to Independent Review Act, MCL 550.1901 *et seq.*

The Commissioner notified Golden Rule Insurance Company (Golden Rule) of the external review request and asked for the information it used to make its final adverse determination. On August 22, 2011, Golden Rule furnished the requested information. After a preliminary review of the material received, the Commissioner accepted the Petitioner's request on August 25, 2011.

Because medical issues are involved, the Commissioner assigned the case to an independent review organization which provided its analysis and recommendations on September 13, 2011.

II. FACTUAL BACKGROUND

The Petitioner receives health benefits as an eligible dependent under an association group policy that is underwritten by Golden Rule. Her benefits are defined in the certificate of insurance (the certificate).

In May 2009, the Petitioner was diagnosed with colon cancer and underwent a colon resection. In September 2010 she had complaints of pain, an abdominal mass, bloating with increased bladder pressure, increased constipation and thinning of her stools, and was found to have ovarian cancer. She had a total abdominal hysterectomy/bilateral salpingo-oophorectomy (TAH/BSO).

The Petitioner's physician sent a specimen of the ovarian mass to XXXXX, Inc., for a ChemoFx Assay to help develop a personalized course of treatment for the Petitioner. The results of the assay revealed metastatic colon cancer to the ovary and not an ovarian primary malignancy.

Golden Rule denied coverage for the ChemoFx Assay, ruling it was not medically necessary. The Petitioner appealed the denial through Golden Rule's internal grievance process. At the conclusion of that process, Golden Rule issued a final adverse determination dated June 30, 2011, affirming its denial of coverage.

III. ISSUE

Did Golden Rule correctly deny coverage for the ChemoFx Assay?

IV. ANALYSIS

Petitioner's Argument

The Petitioner's representative explained that the ChemoFx Assay is a diagnostic test developed to improve the outcomes of cancer patients by providing personalized medicine solutions aimed at increasing the quality of life and improving cancer survival rates. The representative argues that the ChemoFx Assay is widely used and should be considered a medical necessity for the Petitioner because she has been diagnosed with a terminal illness.

The representative states the test is used to gather crucial information for use in chemotherapy selection, to personalize the treatment plan and reduce the devastating affects of the Petitioner's cancer. The representative advised the information could not be obtained any other way.

In an appeal letter dated August 16, 2011, the Petitioner's authorized representative wrote:

Ovarian cancer treatment options may include surgery, chemotherapy and radiation therapy. Sometimes a patient will receive a combination of these cancer treatments. Typically, ovarian cancer responds well to chemotherapy treatment. The patient's treatment will depend on disease stage, the histologic cell type, patient age and their overall condition. For ovarian cancer patients receiving

chemotherapy, whether as adjuvant chemotherapy, primary chemotherapy or combination chemotherapy, ChemoFx® can assist physicians in selecting personalized cancer treatment plans. Physicians can use ChemoFx® as a guide by testing multiple chemotherapy drugs on a patient's cancer cells before choosing one for their patient, giving patients a powerful advantage in their fight against cancer.

We believe that after further review you will agree that the ChemoFx® Assay was medically necessary in helping the patient's physician determine which chemotherapies would be most effective for the individual's cancer. Attached are supporting documents for your review.

Respondent's Argument

In its final adverse determination, Golden Rule advised the Petitioner's representative:

Your request has undergone four separate medical reviews. Two of the reviewers were Licensed Board Certified Internal Medicine Physicians specializing in Medical Oncology and two Licensed Board Certified Internal Medicine Physicians specializing in Medical Oncology and Hematology. These reviewers agree that while ChemoFx Assay is not provided as a convenience, it is also not appropriate for the diagnosis and/or symptoms and it exceeds (in scope, duration and/or intensity) the level of care which is needed to provide safe, adequate and appropriate diagnosis and treatment. We concur with the opinions of the reviewers and considered in conjunction with the [Petitioner's] Certificate of Insurance, benefits are not available as the services do not meet the Certificate definition of medically necessary.

Commissioner's Review

The Petitioner's certificate (p. 30) excludes coverage for services that are not medically necessary:

GENERAL EXCLUSIONS AND LIMITATIONS

* * *

Even if not specifically excluded by the policy, no benefit will be paid for a service or supply unless it is:

* * *

(B) *Medically necessary* to the diagnosis or treatment of an *injury* or *illness*.

The Certificate has this definition of "medically necessary":

"Medically necessary" means a treatment, test, procedure or confinement that is

necessary and appropriate for the diagnosis or treatment of an *illness* or *injury*.

This determination will be made by us based on our consultation with an appropriate medical professional. A treatment, test, procedure or confinement will not be considered *medically necessary* if: (A) it is provided only as a convenience to the *covered person* or provider; (B) it is not appropriate for the *covered person's* diagnosis or symptoms; or (C) it exceeds (in scope, duration, or intensity) that level of care which is needed to provide safe, adequate and appropriate diagnosis or treatment to the *covered person*.

The fact that any particular *doctor* may prescribe, order, recommend, or approve a treatment, test, procedure, or confinement does not, of itself, make the treatment, test, procedure or confinement *medically necessary*.

To resolve the question of whether the ChemoFx Assay was medically necessary for the treatment of the Petitioner's condition, the matter was presented to an independent review organization (IRO) for analysis as required by Section 11(6) of the Patient's Right to Independent Review Act, MCL 550.1911(6).

The IRO reviewer is an actively practicing physician who is board certified in obstetrics and gynecology with a subspecialty in gynecologic oncology, is a member of several national associations and societies, is an assistant professor at a major medical school, and is published in peer reviewed medical literature. The IRO reviewer, who is familiar with the medical management of patients with the Petitioner's condition, provided the following analysis and conclusion:

Reviewer's Decision and Principal Reasons for the Decision:

It is the determination of this reviewer that the Chemo Fx Assay is experimental or investigational given that it is not approved by the Food and Drug Administration (FDA); it lacks data from peer reviewed literature to prove its efficacy; and the assay would be appropriate to use for the treatment of metastatic colon cancer or ovarian cancer, only in the setting of a clinical trial requiring IRB approval. Therefore, the Chemo Fx Assay is not medically necessary in this enrollee's case.

Clinical Rationale for the Decision:

The enrollee has metastatic colon cancer to the ovary and not a primary ovarian cancer. . . . The standard of care for metastatic colon cancer to the ovary, surgically excised, in the absence of any other evidence of metastatic disease would be to consider close follow up or surveillance. For patients with metastatic colon cancer to the ovary, with evidence of metastatic disease after TAH/BSO, standard therapy would be to consider treatment with chemotherapy and an Avastin based regimen. However, the ChemoFx Assay lacks data to show efficacy

for the treatment of metastatic colon cancer. That is, there is no data to show that health outcomes or overall survival is better for patients with metastatic colon cancer who have their cancer treated with chemotherapy regimens chosen based on the assay results vs those who have their treatment chosen based on standard of care regimens.

The Commissioner is not required in all instances to accept the IRO's recommendation. However, the recommendation is afforded deference by the Commissioner. In a decision to uphold or reverse an adverse determination, the Commissioner must cite "the principal reason or reasons why the Commissioner did not follow the assigned independent review organization's recommendation." MCL 550.1911(16)(b). The IRO's analysis is based on extensive experience, expertise and professional judgment and the Commissioner can discern no reason why the IRO's recommendation should be rejected in the present case.

The Commissioner finds that Golden Rule's denial of coverage for the Petitioner's ChemoFx Assay is consistent with the terms of the certificate.

V. ORDER

The Commissioner upholds Golden Rule Insurance Company's final adverse determination of June 30, 2011. Golden Rule is not required to cover the Petitioner's ChemoFx Assay.

This is a final decision of an administrative agency. Under MCL 550.1915, any person aggrieved by this Order may seek judicial review no later than 60 days from the date of this Order in the circuit court for the county where the covered person resides or in the circuit court of Ingham County. A copy of the petition for judicial review should be sent to the Commissioner of Financial and Insurance Regulation, Health Plans Division, Post Office Box 30220, Lansing, MI 48909-7720.

R. Kevin Clinton
Commissioner